MAR 1 2002

4.0 SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: Diagnostic Systems Laboratories, Inc.
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FDA Registration # 1628193

Contact: Carroll Potts
Manager of Regulatory Affairs
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Date of Summary: December 31, 2001
Device Trade Name: DSL ACTIVE™ Free ß-hCG ELISA Kit
Classification Name: Enzymeimmunoassay, Human Chorionic Gonadotropin
Analyte Code and Name: Human Chorionic Gonadotropin (hCG)
Regulatory Class: II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K020128

Test Description:

The DSL-10-8500 ACTIVE™ Free β-hCG ELISA kit was developed for the quantitative measurement of Free β-subunit of human chorionic gonadotropin (hCG) in human serum. Human chorionic gonadotropin (hCG) is a glycoprotein secreted by the trophoblastic cells of the placenta. hCG is composed of two dissimilar non-covalently linked polypeptides known as the α- and β-subunits [1]. The α-subunit is very similar to the α-chain of lutropin (hLH), follitropin (hFSH), and thyrotropin (hTSH). The β-subunit is responsible for the biological activity of this hormone [1,2].

The primary utility of hCG measurement is for the early detection and monitoring of pregnancy, and pregnancy related disorders. Healthy, non-pregnant individuals have low (< 5 IU/L) to undetectable hCG concentrations in serum. During pregnancy, hCG concentrations increase to about 50 IU/L in the first week after conception and double every 1.5 to 3 days for the first six weeks. Levels continue to rise until the end of the first trimester, then gradually fall to a lower level for the remainder of the pregnancy. After delivery, hCG returns to < 5 IU/L and is usually undetectable several days postpartum.

Initial immunoassays for hCG, although capable of achieving sufficient sensitivity for early detection of pregnancy, suffered from a significant degree of cross-reactivity with pituitary glycoproteins, particularly hLH.

The DSL ACTIVE® Free ß-hCG ELISA is a two-site ELISA assay in which the free ß-hCG to be measured is "sandwiched" between two antibodies. The first antibody is immobilized to the inside wall of the microtitration well, the other antibody is conjugated to the enzyme horseradish peroxidase for detection. The analyte present is bound by both the antibodies to form a "sandwiched" complex. Unbound materials are removed by washing the wells. The resultant is analyzed in a spectrophotometer for absorbance. The amount of bound Free β-hCG is directly proportional to the concentration of the Free β-hCG present in the sample. The antibodies were raised against sterically remote epitopes on the beta subunit of hCG, such that in intact hCG molecules, these antibody recognition sites are not available. The DSL ACTIVE® Free ß-hCG ELISA is very specific for free ß-hCG without cross-reactivity or interference due to LH, FSH, AFP, TSH or prolactin.

Intended Use:

The DSL-10-8500 ACTIVE™ Free β-hCG ELISA assay is intended for the quantitative determination of Free β-hCG in human serum. It is intended for in vitro diagnostic use by professional laboratory personnel as an aid in the detection of pregnancy.

Substantial Equivalence:

The DSL-10-8500 ACTIVE™ Free β-hCG ELISA is substantially equivalent to the DSL-8300 Intact-hCG IRMA.

To demonstrate substantial equivalence between the two assays, pregnant patient samples (n=98) were collected and assayed using both methods. Samples were chosen based on expected hCG levels so that samples with low, intermediate and high levels would be evaluated. Linear regression analysis of the results obtained for the comparison gave the equation:
DSL-10-8500 = 0.007(DSL-8300) - 2.7, with a correlation coefficient of $r = 0.82$ and $p < 0.001$.

Additionally, serum samples from 20 normal males and 20 non-pregnant females were analyzed for Free β-hCG with the DSL-10-8500 ACTIVE™ Free β-hCG ELISA, where 95% of male values were < 1 mIU / mL and 95% of female values were < 1 mIU / mL. Therefore, the physiological profiles for intact hCG and Free β-hCG remain parallel throughout pregnancy.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 2002

Ms. Carroll Potts, M.S.
Manager of Regulatory Affairs
Diagnostic Systems Laboratories, Inc.
445 Medical Center Blvd
Webster, TX 77598

Re: k020128
Trade/Device Name: DSL ACTIVE™ Free β-hCG ELISA
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: February 8, 2002
Received: February 11, 2002

Dear Ms.Potts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.0 INDICATIONS FOR USE

510 (k) Number (if known): K 020128

Device Name: DSL ACTIVE™ Free ß-hCG ELISA

Indications for Use:

The DSL-10-8500 ACTIVE™ Free β-hCG Enzyme-Linked Immunosorbent Assay (ELISA) kit provides materials for the quantitative measurement of Free β-subunit of human chorionic gonadotropin (hCG) in serum. This assay is intended for *in vitro* diagnostic use as an aid in the detection of pregnancy.

Susan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020128

(Please Do Not Write Below This Line. Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The Counter Use** _____
(Per 21 CFR 801.109)

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